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REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 1.28

QUALITY ASSURANCE PROGRAM REQUIREMENTS (DESIGN AND CONSTRUCTION)
(Task RS 002-5)

A. INTRODUCTION

Nuclear power plants and fuel reprocessing plants include structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. Appendix B to 10 CFR Part 50 establishes quality assurance requirements for the design, construction, and operation of those structures, systems, and components. The pertinent requirements of Appendix B apply to all activities affecting the safety-related functions of those structures, systems, and components. These activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

This regulatory guide describes a method acceptable to the NRC staff for complying with the provisions of Appendix B with regard to establishing and implementing the requisite quality assurance program for the design and construction of nuclear power plants. Guidance for the establishment and execution of quality assurance programs during operation and decommissioning of nuclear power plants have been or will be addressed in separate regulatory guides. Similarly, quality assurance provisions concerning fuel cycle facilities have been or will be addressed in separate regulatory guides.

Any information collection activities mentioned in this regulatory guide that may be subject to the Paperwork Reduction Act of 1980 (44 U S.C. 3501 et seq.) have been reviewed by the Office of Management and Budget and were included in OMB Approval No. 3150-0011.

The Advisory Committee on Reactor Safeguards has been consulted concerning this guide and has concurred in the regulatory position.

B. DISCUSSION

Regulatory Guide 1.28 (Safety Guide 28) was issued in June 1972 and endorsed the general requirements and guidelines for establishing and executing a quality assurance program during the design and construction phases of nuclear power plants provided in ANSI N45.2-1971,[1] "Quality Assurance Program Requirements for Nuclear Power Plants." This standard had been developed by Subcommittee N45-2.7 (formerly N45-3.7) of the American National Standards Committee N45, Reactor Plants and Their Maintenance, and provided general requirements for establishing and executing a quality assurance program during the design, construction, and operation of nuclear power plants. ANSI N45.2-1971 was later revised to update its requirements and to expand its applicability to other nuclear facilities that were subject to Appendix B to 10 CFR Part 50. That revised standard was subsequently approved and designated ANSI/ASME N45.2-1977,[1] "Quality Assurance Program Requirements for Nuclear Facilities," by the American National Standards Institute (ANSI) on April 7, 1977. Revision 1 to Regulatory Guide 1.28 was issued for public comment in March 1978. With supplemental provisions, it proposed endorsement of the quality assurance program requirements in ANSI/ASME N45.2-1977 for the design and construction phases of nuclear power plants. In February 1979, the NRC issued Revision 2 to Regulatory Guide 1.28, which, with supplemental provisions, also endorsed the quality assurance program requirements of ANSI/ASME N45.2-1977 for the design and construction phases of nuclear power plants.

The American Society of Mechanical Engineers (ASME) Committee on Nuclear Quality Assurance has prepared a new standard that includes requirements and guidance for establishing and executing quality assurance

*The substantial number of changes in this revision has made it impractical to indicate the changes with lines in the margins.

[1]Copies may be obtained from the American Society of Mechanical Engineers, 345 East 47th Street, New York, New York 10017.

programs for the design, construction, operation, and decommissioning of nuclear facilities. This standard is based on the contents of ANSI N46.2-1978, ANSI/ASME N45.2-1977, and the following standards in the ANSI N45.2 series:[1]

N45.2.6 "Qualification of Inspection, Examination, and Testing Personnel for Nuclear Power Plants"

N45.2.9 "Requirements for Collection, Storage and Maintenance of Quality Assurance Records for Nuclear Power Plants"

N45.2.10 "Quality Assurance Terms and Definitions"

N45.2.11 "Quality Assurance Requirements for the Design of Nuclear Power Plants"

N45.2.12 "Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants"

N45.2.13 "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants"

N45.2.23 "Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants"

The standard that evolved was approved and designated ANSI/ASME NQA-1-1979,[1] "Quality Assurance Program Requirements for Nuclear Power Plants," by ANSI on July 24, 1979. Three addenda to ANSI/ASME NQA-1-1979 were developed by the American Society of Mechanical Engineers. These addenda, contained in ANSI/ASME NQA-1a-1981, NQA-1b-1981, and NQA-1c-1982, were issued by ANSI on April 30, 1981, January 31, 1982, and December 31, 1982, respectively, following approval by the Main Committee of the ASME Committee on Nuclear Quality Assurance. On July 1, 1983, ANSI/ASME NQA-1-1983 was issued. It incorporated ANSI/ASME NQA-1-1979 and the NQA-1a-1981, NQA-1b-1981, and NQA-1c-1982 Addenda into the 1983 edition without changing any of the previous requirements, supplements, or appendices described in ANSI/ASME NQA-1-1979 and addenda. On December 31, 1983, after approval by the Main Committee of the ASME Committee on Nuclear Quality Assurance, the ANSI/ASME NQA-1a-1983 Addenda were issued. They clarified previous sections of ANSI/ASME NQA-1-1983. The standard notes that addenda will be published up to the publication date of the next edition of the standard. The NRC staff will evaluate addenda and subsequent editions of NQA-1 after their issuance to determine whether a revision to this guide would be appropriate.

ANSI/ASME NQA-1-1983 has been organized into three main sections: (1) Basic Requirements, (2) Supplements, and (3) Appendices. The Basic Requirements section sets forth basic requirements for establishing and executing quality assurance programs. The Supplements section amplifies the individual requirements of the Basic Requirements section. The Appendices section provides nonmandatory guidance for meeting the Basic Requirements and Supplements sections.

The intent of ANSI/ASME NQA-1-1983 was to consolidate the quality assurance programmatic standards to reduce redundancy without changing the overall intent of the standard. This Revision 3 to Regulatory Guide 1.28 was developed to endorse ANSI/ASME NQA-1-1983. In its development, the NRC staff intended it to be equivalent to the methods described in Regulatory Guides 1.28 (Rev. 2), 1.58 (Rev. 1), 1.64 (Rev. 2), 1.74, 1.88 (Rev. 2), 1.123 (Rev. 1), 1.144 (Rev. 1), and 1.146. To accomplish this equivalency, parts of the "nonmandatory guidance" in ANSI/ASME NQA-1-1983 that were previously requirements in the ANSI/ASME N45.2 series were included as regulatory positions in Proposed Revision 3 to Regulatory Guide 1.28, which was issued in March 1981 for public comment. Also, several of the previous regulatory positions endorsing the ANSI/ASME N45.2-series standards were included as regulatory positions in Proposed Revision 3 to Regulatory Guide 1.28.

Based on public comments and further NRC staff review, the regulatory positions have been reassessed to determine their value and impact on nuclear power plant safety. In this reassessment, the advantage of minimizing the number of exceptions taken to a national standard was considered. Consequently, a number of regulatory positions that were intended as clarifications to provisions of the standard were reconsidered and deleted from the regulatory position. The guide now retains positions in only those areas in which the staff believes additional guidance is necessary. Retaining these positions also attempts to avoid building in more differences among facilities than already exist. The safety advantage of these positions will be to encourage greater standardization of quality assurance practices. Although the standard contains general provisions covering the subjects addressed in the regulatory positions, it does not provide detailed guidance for implementing its general requirements. Without these positions, detailed case-by-case reviews will be necessary in the licensing review process, and the likelihood of unnecessary differences between facilities is increased.

Although ANSI/ASME NQA-1-1983 provides requirements and guidance for the establishment and execution of quality assurance programs during the design, construction, operation, and decommissioning of nuclear facilities, this Revision 3 to Regulatory Guide 1.28, with supplemental provisions, addresses only those portions of ANSI/ASME NQA-1-1983 applicable to the design and construction phases of nuclear power plants. Updated guidance for complying with the Commission's regulations with regard to quality assurance program requirements for the operations phase of nuclear power plants

will be provided in Regulatory Guide 1.33, Revision 3, "Quality Assurance Program Requirements (Operation)," which is presently undergoing NRC staff review and is expected to endorse, with supplemental provisions, ANSI/ANS-3.2-1982,[2] "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants."

Regulatory Guide 1.8, "Personnel Selection and Training," provides guidance on personnel selection and training, including the qualifications of certain operators, technicians, and maintenance personnel who may perform inspections and tests during preoperational, startup, and operational testing. The requirements of Supplement 2S-1 and recommendations of Appendix 2A-1 in NQA-1 also provide guidance on personnel qualifications. Personnel performing inspection and testing that are qualified to the guidance contained in Regulatory Guide 1.8[3] need not be qualified in accordance with the requirements of NQA-1. It is not the intent that such personnel be qualified in accordance with both Regulatory Guide 1.8 and NQA-1.

In the development of Regulatory Position 2, "Quality Assurance Records," Section 3 of Appendix 17A-1 was used in the preparation of Table 1 in accordance with the requirements for records classification defined in paragraph 2.7 of Supplement 17S-1. Although Table 1 provides a list of nonpermanent and lifetime records and their respective retention times, the emphasis should be placed on the quality of the product rather than the records generated.

If an applicant or licensee indicates to the NRC that it will conform to the recommendations of this regulatory guide and it does not qualify its willingness to conform, it has agreed to comply with the requirements of ANSI/ASME NQA-1-1983 and the ANSI/ASME NQA-1a-1983 Addenda, as supplemented or modified by the regulatory positions in this guide.

An applicant or licensee that has committed itself to the recommendations of this regulatory guide is responsible for ensuring that the requirements of ANSI/ASME NQA-1-1983 and the ANSI/ASME NQA-1a-1983 Addenda, as supplemented or modified by the regulatory positions of this guide, are met by its suppliers to the extent necessary.

C. REGULATORY POSITION

The basic and supplementary requirements that are included in ANSI/ASME NQA-1-1983 and the ANSI/ASME NQA-1a-1983 Addenda for the establishment and execution of quality assurance programs during the design and construction phases of nuclear power plants are acceptable to the NRC staff and provide an adequate basis for complying with the pertinent quality assurance requirements of Appendix B to 10 CFR Part 50, subject to the additions and modifications to ANSI/ASME NQA-1-1983 and the ANSI/ASME NQA-1a-1983 Addenda identified below.

1. QUALIFICATION OF INSPECTION AND TEST PERSONNEL

Appendix 2A-1, "Nonmandatory Guidance on the Qualifications of Inspection and Test Personnel," provides guidance on the qualifications of inspection and test personnel. The provisions of Appendix 2A-1 (or acceptable alternatives) should be met as part of Supplement 2S-1, "Supplementary Requirements for the Qualification of Inspection and Test Personnel."

2. QUALITY ASSURANCE RECORDS

Section 2.8, "Retention of Records," of Supplement 17S-1, "Supplementary Requirements for Quality Assurance Records," states that the retention period for nonpermanent records is required to be established in writing. Programmatic nonpermanent records[4] should be retained for at least 3 years and product nonpermanent records[5] should be retained for at least 10 years or the life of the item if less than 10 years. For programmatic nonpermanent records, the retention period should be considered to begin upon completion of the activity. For product nonpermanent records generated before commercial operation begins, the retention period should be considered to begin upon completion of delivery. In addition, product and programmatic nonpermanent records should be retained at least until the date of issuance of the full-power operating license of the unit. Table 1 provides a list of nonpermanent and lifetime records and their respective retention times. Although Table 1 is intended to be a comprehensive list, it is the responsibility of the owner to assure itself, in accordance with Criterion 17 of Appendix B to 10 CFR Part 50, that sufficient records are maintained to furnish evidence of activities affecting quality. It should be recognized that the nomenclature of these records may vary. For records not listed in Table 1, the type most nearly describing the record in question should be followed with respect to its retention period.

[2]Copies may be obtained from the American Nuclear Society, 555 North Kensington Avenue, La Grange Park, Illinois 60525.

[3]In response to Section 306 of Public Law 97-425, the lessons learned from the Three Mile Island accident, public comments, and additional staff review, a third Proposed Revision 2 to Regulatory Guide 1.8 entitled "Qualification and Training of Personnel for Nuclear Power Plants" was issued for public comment in January 1985 with the identification number Task OL 403-5.

[4]Programmatic nonpermanent records are those documents that were used to prescribe activities affecting quality but that are not considered permanent records. Such records include documents prescribing the planning, execution, and auditing of activities affecting quality. Records such as audit checklists, audit results, and actual examinations used to qualify inspection and test personnel are included in this category.

[5]Product nonpermanent records document that specific structures, systems, and components of a nuclear power plant have been designed and constructed in accordance with applicable requirements but are such that it is not necessary to retain them as lifetime records. These records include design verification data, receiving records, calibration records, maintenance records, inspection records, radiographs not associated with inservice inspection, and test records that are not otherwise designated as lifetime records.

3. AUDITS

Section 2, "Scheduling," of Supplement 18S-1, "Supplementary Requirements for Audits," requires audits to be scheduled in a manner that provides coverage and coordination with ongoing quality assurance program activities. The following guidelines are considered acceptable for scheduling audits:

3.1 Internal Audits

Applicable elements of an organization's quality assurance program should be audited at least once each year or at least once during the life of the activity, whichever is shorter. In determining the scope of the audit, an evaluation of the activity being audited may be useful. The evaluation may include results of previous quality assurance program audits and the results of audits from other sources, including the nature and frequency of identified deficiencies and any significant changes in personnel, organization, or quality assurance program.

3.2 External Audits

After the award of a contract, the applicant or licensee may determine, based on the evaluation conducted in accordance with Section 5.1 of Appendix 4A-1, that external audits are not necessary for procuring items that are (1) relatively simple and standard in design, manufacturing, and testing and (2) adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery.

For other procurement actions not covered by the above exceptions, audits should be conducted as described below.

1. The applicant or licensee should either audit its supplier's quality assurance program on a triennial basis or arrange for such audit. In either case, the audit should be implemented in accordance with Supplement 18S-1 of ANSI/ASME NQA-1-1983. The triennial period begins when an audit is performed. An audit may be performed when the supplier has completed sufficient work to demonstrate that its organization is implementing a quality assurance program that has the required scope for purchases placed during the triennial period. If a subsequent contract or a contract modification significantly enlarges the scope of or changes the methods or controls for activities performed by the same supplier, an audit of the modified requirements should be conducted, thus starting a new triennial period. If the supplier is implementing the same quality assurance program for other customers that is proposed for use on the auditing party's contract, the pre-award survey may serve as the first triennial audit if conducted in accordance with the requirements of ANSI/ASME NQA-1-1983. Therefore, when such pre-award surveys are employed as the first triennial audits, they should satisfy the same audit elements and criteria as those used on other triennial audits.

2. The applicant or licensee should perform or arrange for annual evaluations of suppliers. This evaluation should be documented and should take into account, where applicable, (1) review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions; (2) results of previous source verifications, audits, and receiving inspections; (3) operating experience of identical or similar products furnished by the same supplier; and (4) results of audits from other sources, e.g., customer, ASME, or NRC audits.

3. If more than one purchaser buys from a single supplier, a purchaser may either perform or arrange for an audit of the supplier on behalf of itself and other purchasers to reduce the number of external audits of the supplier. The scope of this audit should satisfy the needs of all of the purchasers, and the audit report should be distributed to all the purchasers for whom the audit was conducted. Nevertheless, each of the purchasers relying on the results of an audit performed on behalf of several purchasers remains individually responsible for the adequacy of the audit.

D. IMPLEMENTATION

The methods described in this revision (through endorsement of ANSI/ASME NQA-1-1983 and the ANSI/ASME NQA-1a-1983 Addenda) for complying with the provisions of Appendix B to 10 CFR Part 50 with regard to the establishment and implementation of the requisite quality assurance program are considered to be generally equivalent, from a programmatic standpoint, to the methods described in Revision 2 to Regulatory Guide 1.28 and Regulatory Guides 1.58, 1.64, 1.74, 1.88, 1.123, 1.144, and 1.146 (through endorsement of ANSI/ASME N45.2 and seven programmatic ANSI/ASME N45.2-series standards).

Applicants and licensees that have committed to ANSI/ASME N45.2 and the appropriate ANSI N45.2-series standards as addressed in the applicable regulatory guides may continue to follow ANSI/ASME N45.2 and the appropriate ANSI/ASME N45.2-series standards instead of ANSI/ASME NQA-1-1983. Applicants and licensees may commit to follow either the ANSI/ASME N45.2-series standards or the ANSI/ASME NQA-1-1983 standard but not a combination of the two.

Because ANSI/ASME NQA-1-1983 consolidates ANSI/ASME N45.2 and the seven programmatic ANSI/ASME N45.2-series standards, these standards have been replaced with ANSI/ASME NQA-1-1983. Consequently, except in those cases in which an applicant or licensee proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the method described in this revision will be used in the evaluation of all new (1) construction permit applications, (2) standard design approvals that can be referenced in construction permit applications, and (3) licenses to manufacture.

TABLE 1

Retention Times for Lifetime and Nonpermanent Records

Record Type	Lifetime	Nonpermanent* 3 yr	Nonpermanent* 10 yr
1. Design Records			
Applicable codes and standards used in design	X		
Design drawings	X		
Design calculations and record of checks	X		
Approved design change requests	X		
Design deviations and nonconformances	X		
Design reports	X		
Design verification data	X		
Design specifications and amendments	X		
Safety analysis report	X		
Certified stress reports for code items	X		
System descriptions	X		
System process and instrumentation diagrams	X		
Technical analysis, evaluations, and reports	X		
Master change record	X		
Reliability analysis, evaluation, and reports	X		
Equipment qualification documentation	X		
Design review reports			X
Design procedures and manuals		X	
Design control procedures		X	
Reports of engineering surveillance of field activity		X	
2. Procurement Records			
Procurement specification	X		
Purchase order (unpriced) including amendments	X		
Procurement procedures		X	
Purchaser's pre-award quality assurance survey		X	
Receiving records		X	
Supplier's quality assurance program manual		X	
Source surveillance data plans, audit and surveillance reports		X	
3. Manufacturing Records			
Applicable code data reports	X		
As-built drawings and records	X		
Certificate of compliance	X		
Eddy-current examination final results	X		
Electrical control verification test results	X		
Ferrite test results	X		
Heat treatment records	X		
Liquid penetrant examination final results	X		
Location of weld filler material	X		
Magnetic particle examination final results	X		
Major defect repair records	X		
Material properties records	X		
Nonconformance reports	X		
Performance test procedure and results records	X		
Pipe and fitting location report	X		
Pressure test results (hydrostatic or pneumatic)	X		
Radiograph review records	X		
Ultrasonic examination final results	X		

TABLE 1 (Continued)

Record Type	Lifetime	Nonpermanent* 3 yr	Nonpermanent* 10 yr
3. Manufacturing Records (Continued)			
Welding procedures	X		
Radiographs not required by ASME Section XI			X
Certificate of inspection and test personnel qualification		X	
Cleaning procedures		X	
Eddy-current examination procedure		X	
Ferrite test procedure		X	
Forming and bending procedure qualifications		X	
Heat treatment procedures		X	
Hot bending procedure		X	
Inspection and test instrumentation and tooling calibration records (after last calibration)		X	
Liquid penetrant examination procedure		X	
Magnetic particle examination procedure		X	
Packaging, receiving, storage procedures		X	
Product equipment calibration procedure		X	
QA manuals, procedures, and instructions		X	
Radiographic procedures		X	
Ultrasonic examination procedures		X	
Welding materials control procedures		X	
Welding procedure qualifications and data reports		X	
Work processing and sequencing documents		X	
Product equipment calibration records (after last calibration)		X	
4. Installation Construction Records			
4.1 Receiving and Storage			
Nonconformance reports	X		
Inspection reports for stored items		X	
Receipt inspection reports on items		X	
Receiving, storage, and inspection procedures		X	
Storage inventory and issuance records		X	
Vendor quality assurance releases		X	
4.2 Civil			
Checkoff sheets for tendon installation	X		
Concrete cylinder test reports and charts	X		
Concrete design mix reports	X		
Concrete placement records	X		
Inspection reports for channel pressure tests	X		
Material property reports on containment liner and accessories	X		
Material property reports on metal containment shell and accessories	X		
Material property reports on reinforcing steel	X		
Material property reports on reinforcing steel splice sleeve material	X		
Material property reports on steel embedments in concrete	X		
Material property reports on structural steel and bolting	X		
Material property reports on tendon fabrication material	X		
Pile drive log	X		
Pile loading test reports	X		
Procedure for containment vessel pressure proof test and leak-rate tests and results	X		

TABLE 1 (Continued)

Record Type	Lifetime	Nonpermanent* 3 yr	Nonpermanent* 10 yr
4.2 Civil (Continued)			
Reports for periodic tendon inspection	X		
Reports of high-strength bolt torque testing	X		
Soil compaction test reports	X		
Aggregate test reports			X
Batch plant operation reports			X
Cement grab sample reports			X
Material property reports on steel piling			X
Mix water chemical analysis			X
Releases to place concrete			X
Slump test results			X
User's tensile test reports on reinforcing steel			X
User's tensile test reports on reinforcing steel splices			X
4.3 Welding			
Ferrite test results	X		
Heat treatment records	X		
Liquid penetrant test final results	X		
Material property records	X		
Magnetic particle test final results	X		
Major weld repair procedure and results	X		
Radiograph review records and final results	X		
Ultrasonic test final results	X		
Weld location diagrams	X		
Weld procedures	X		
Welding filler metal material reports	X		
Ferrite test procedures		X	
Heat treatment procedures		X	
Liquid penetrant test procedures		X	
Magnetic particle test procedures		X	
Radiographic test procedures		X	
Ultrasonic test procedures		X	
Welding materials control procedures		X	
Welding personnel qualifications		X	
Weld fitup reports			X
Weld procedure qualifications and results			X
4.4 Mechanical			
Cleaning procedures and results	X		
Installed lifting and handling equipment procedures, inspection, and test data	X		
Lubrication procedures	X		
Material properties records	X		
Pipe and fitting location reports	X		
Pipe hanger and restraint data	X		
Safety valve response test procedures	X		
Code data reports	X		
Pressure test results (hydrostatic or pneumatic)		X	
Chemical composition user's test (grab samples) for thermal insulation			X
Chemical tests of water used for mixing insulation cement			X
Data sheets or logs on equipment installation, inspection, and alignment			X

TABLE 1 (Continued)

Record Type	Lifetime	Nonpermanent* 3 yr	Nonpermanent* 10 yr
4.4 Mechanical (Continued)			
Documentation of system checkoffs (logs or data sheets)			X
Material property test reports for thermal insulation			X
Safety valve response test results			X
Cleaning procedures		X	
Construction lifting and handling equipment test procedures		X	
Erection procedures for mechanical components		X	
Hydrotest procedures		X	
4.5 Electrical and Instrumentation and Control			
Cable pulling tension data	X		
Cable separation data	X		
Cable terminating procedures	X		
Certified cable test reports	X		
Relay test procedures and test results	X		
Voltage breakdown test results on liquid insulation	X		
Cable pulling procedures		X	
Cable separation checklists		X	
Instrument calibration results (after last calibration)		X	
Documentation of testing performed after installation and prior to conditional acceptance of systems			X
Field workmanship checklist or equivalent logs			X
Reports of preinstallation tests			X
4.6 General			
As-built drawings and records	X		
Final inspection reports and releases	X		
Nonconformance reports	X		
Specifications and drawings	X		
Index system to record file	X		
Quality assurance and quality control manuals		X	
Fire protection reports	X		
Security plan procedures and activities	X		
Emergency plan, procedures, and activities	X		
Evaluation of results of reportable safety concerns as required by regulations	X		
Calibration reports for measuring and test equipment and instruments (after last calibration)		X	
Calibration procedures for measuring and test equipment and instruments		X	
Certificate of inspection and test personnel qualification		X	
Field audit reports		X	
Field quality assurance manuals		X	
Quality assurance system audit reports and related correspondence		X	
Special tool calibration records (after last calibration)		X	
5. Preoperational and Startup Test Records			
Final system adjustment data	X		
Initial plant loading data	X		
Plant load ramp change data	X		
Plant load step change data	X		

TABLE 1 (Continued)

Record Type	Lifetime	Nonpermanent* 3 yr	Nonpermanent* 10 yr
j. Preoperational and Startup Test Records (Continued)			
Preoperational test procedures and results	X		
Reactor protection system tests and results	X		
Startup test procedures and results	X		
Inservice inspection reports	X		
Records of reactor tests and experiments	X		
Records and logs of maintenance activities, inspections, repair, and replacement of principal items of structures, systems, and components	X		
Automatic emergency power source transfer procedures and results			X
Initial heatup, hot functional, and cooldown procedures and results			X
Initial reactor criticality test procedures and results			X
Instrument AC system and inverter test procedures and reports			X
Main and auxiliary power transformer test procedures and results			X
Offsite power source energizing procedures and test reports			X
Onsite emergency power source energizing procedure and test reports			X
Primary and secondary auxiliary power test procedures and results			X
Startup logs			X
Station battery and DC power distribution test procedures and reports			X
Water chemistry report			X
Records of reviews performed for changes made to procedures or equipment or reviews of tests and experiments			X
Startup problems and resolutions			X
Flushing results			X
Power transmission substation test procedures and results		X	
Surveillance activities, inspections, and calibrations required by the technical specifications records		X	
System lubricating oil flushing procedures		X	
Flushing procedures		X	
Pressure test procedures		X	
Periodic checks, inspections, and calibrations performed to verify that surveillance requirements are being met		X	

*Table 1 is to be used in conjunction with Regulatory Position C.2, which states that nonpermanent records should be retained at least until the date of issuance of the full-power operating license of the unit.

REGULATORY ANALYSIS

1. STATEMENT OF THE PROBLEM

Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," sets forth the quality assurance requirements for the design, construction, and operation of those structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public.

Current guidance on controls the NRC staff considers acceptable for complying with Appendix B to 10 CFR Part 50 concerning programmatic quality assurance requirements during design and construction is provided in a number of regulatory guides that endorse the standard ANSI/ASME N45.2-1977, "Quality Assurance Program Requirements for Nuclear Facilities," and seven N45.2-series standards that cover specific quality assurance topics. A new standard, ANSI/ASME NQA-1-1979, approved by the American National Standards Institute on July 24, 1979, conconsolidates ANSI/ASME N45.2-1977 and these seven N45.2-series standards. The intent of ANSI/ASME NQA-1-1979 was to consolidate the programmatic standards to avoid redundancy without changing their intent. ANSI/ASME NQA-1-1979 is a second generation standard in which industry experience is reflected in changing certain controls and also eliminating certain activities considered to be ineffective in enhancing quality or the overall effectiveness of the program. ANSI/ASME NQA-1-1979 was developed through a consensus agreed to by the American National Standards Institute. On July 1, 1983, NQA-1-1979 and the NQA-1a-1981, NQA-1b-1981, and NQA-1c-1982 Addenda were incorporated into NQA-1-1983 without changing any of the requirements, supplements, or appendices described in ANSI/ASME NQA-1-1979.

As encouraged by the Office of Management and Budget (OMB) Circular No. A-119, "Federal Participation in the Development and Use of Voluntary Standards," which was published as a final rule in the *Federal Register* November 1, 1982 (47 FR 49496), several NRC representatives participated in the development of ANSI/ASME NQA-1-1983. Since ANSI/ASME NQA-1-1983 represents a consolidation of the seven programmatic N45.2-series standards, these standards along with ANSI/ASME N45.2-1977 will not be revised to incorporate any new positions and will eventually be replaced with ANSI/ASME NQA-1-1983 and the ANSI/ASME NQA-1a-1983 Addenda. This standard is now published in its final form and the NRC must decide what action to take concerning endorsement of the standard. The consequences of the NRC staff taking no action in the development or endorsement of the standard would result in the NRC staff having to either ignore the NQA-1 effort and continue to rely on Revision 2 of Regulatory Guide 1.28 (which in essence means living with ANSI/ASME N45.2-1977 and the seven daughter standards) or develop its own guidance or standard to achieve a consolidated document and minimize redundancy.

2. OBJECTIVES

Proposed Revision 3 to Regulatory Guide 1.28 endorsing ANSI/ASME NQA-1-1983 focuses on the following three objectives:

1. Endorse the consolidation of ANSI/ASME N45.2 and the seven ANSI/ASME N45.2-series standards into one document, thus eliminating certain redundancies and certain activities.

2. Consolidate the eight applicable NRC regulatory guides endorsing the above ANSI/ASME standards into one document.

3. Reflect current NRC guidance, from a programmatic standpoint, concerning quality assurance during design and construction of nuclear power plants and fuel reprocessing facilities.

In developing Revision 3 to Regulatory Guide 1.28 (through endorsement of ANSI/ASME NQA-1-1983), it was the intent that Revision 3 would be equivalent to the methods described by Revision 2 to Regulatory Guide 1.28 and Regulatory Guides 1.58, 1.64, 1.74, 1.88, 1.123, 1.144, and 1.146 (through endorsement of ANSI/ASME N45.2 and the programmatic N45.2-series standards). In order to achieve this equivalence, parts of the "nonmandatory guidance" of ANSI/ASME NQA-1-1983 that were previously requirements in the ANSI/ASME N45.2-series standards will be treated the same as requirements of ANSI/ASME NQA-1-1983, i.e., a commitment to follow Regulatory Guide 1.28, Revision 3, without exceptions will be a commitment to follow the requirements of ANSI/ASME NQA-1-1983 and the endorsed "nonmandatory guidance" of the standard. In addition, some of the regulatory positions related to the ANSI/ASME N45.2-series standards were retained in order to achieve equivalence and provide consistency in the quality assurance program review process. The guide does indicate that it describes a method acceptable to the NRC staff for complying with the provisions of Appendix B to 10 CFR Part 50 with regard to the establishment and implementation of a quality assurance program during design and construction of nuclear power plants. This does represent a change from the guide issued for public comment since the present Regulatory Guide 1.28 (Revision 2) references only Appendix B to 10 CFR Part 50, and the references to Appendix A to 10 CFR Part 50 have been deleted from the proposed Revision 3 to Regulatory Guide 1.28. The NRC staff

is currently examining on a generic basis the subject of how to implement the quality assurance provisions of Appendix A to 10 CFR Part 50 for structures, systems, and components important to safety. The subject of application of a quality assurance program for items important to safety but not safety related is being addressed separately by the NRC staff in connection with the January 5, 1984, generic letter to all holders of operating licenses, applicants for operating licenses, and holders of construction permits for power reactors concerning the use of the terms "Important to Safety" and "Safety Related."

3. ALTERNATIVES

The following alternatives were considered with respect to revising Regulatory Guide 1.28:

3.1 Alternative 1

Remain with the NRC regulatory guides presently endorsing ANSI/ASME N45.2 and the seven programmatic daughter standards. Any new or revised quality assurance regulatory positions considered sufficiently important to ensure protection of the public health and safety could be incorporated through appropriate revisions to the applicable quality assurance regulatory guides.

3.2 Alternative 2

Develop a consolidated version of quality assurance guidance for design and construction in the form of a regulatory guide or NUREG-series document.

3.3 Alternative 3

Review NQA-1-1983 and revise Regulatory Guide 1.28 to ensure quality assurance program controls equivalent (from a programmatic standpoint) to those previously endorsed by Revision 2 to Regulatory Guide 1.28.

4. CONSEQUENCES, COSTS, AND BENEFITS OF EACH ALTERNATIVE

4.1 Alternative 1

Benefits: Alternative 1 eliminates the need to devote NRC resources to the review and evaluation of ANSI/ASME NQA-1-1983 in order to formulate NRC positions commensurate with current quality assurance requirements. Licensees, permit holders, vendors, subvendors, and NRC Headquarters and Regional inspection personnel are presently familiar with the quality assurance regulatory guides that endorse the N45.2-series quality assurance standards. Also, industry presently has the N45.2-series standards and NRC regulatory guides that endorse these standards in their possession. Industry and NRC would not be required to spend considerable time, effort, or resources to interpret and implement the regulatory positions endorsing the Basic Requirements, Supplements, and selected "nonmandatory guidance" of ANSI/ASME NQA-1-1983. Also, industry already has these guides and standards at their sites and shops, and their quality assurance manuals and implementing procedures have either incorporated or referenced them in their documents. Consequently, little or no effort would be required of the industry to update should NRC include new positions to existing regulatory guides.

Consequences: ASME has initiated action for ANSI to withdraw the N45.2-series standards that have been consolidated into NQA-1; thus the N45.2-series standards will be replaced with NQA-1. Also, as stated in OMB Circular No. A-119, policy and administrative guidance is provided to Federal agencies on using voluntary standards for procurement and regulatory purposes and participating with private sector organizations to develop such standards as NQA-1. Finally, the 1982 Winter Addenda of the ASME Boiler and Pressure Vessel Code has endorsed ANSI/ASME NQA-1-1979 in Sections III and XI and it is expected they will ultimately endorse ANSI/ASME NQA-1-1983.

Costs: The format and subject matter of existing standards and regulatory guides are readily understandable and usable by the 79 licensees, 63 permit holders, and their approximately 700 vendors. Because the majority of the industry has committed to the existing N45.2-series standards and regulatory guides, it would not result in any increased burden or costs to the industry to continue using these documents.

4.2 Alternative 2

Benefits: From a regulatory viewpoint, this effort would represent precise methods for guidance on how the Commission's quality assurance provisions relating to the design and construction of nuclear power plants must be implemented.

Consequences: This alternative is contrary to the policy expressed in OMB Circular No. A-119 and has the possibility of bureaucratic delays.

Costs: The development of an initial draft of a consolidated quality assurance standard such as ANSI/ASME NQA-1-1983 would take the NRC staff about two months. The resolution of both internal NRC staff and public comments would take about one year for a total cost of approximately $120,000 (2000 hours x $60/hour).

4.3 Alternative 3

Benefits: Since current guidance for quality assurance programs is contained in a series of different standards and corresponding regulatory guides, the proposed action will be of value to the NRC staff owing to the consolidation of a large number of requirements and recommendations concerning quality

assurance into a single document consisting of sections on basic requirements, supplemental requirements, and nonmandatory guidance.

The previous eight quality assurance standards and quality assurance regulatory guides that endorsed these standards consisted of approximately 85 pages and the consolidated documents and proposed regulatory guide would consist of approximately 5 pages for a net reduction of about 80 pages. The previous eight regulatory guides endorsing the standards consolidated into ANSI/ASME NQA-1-1983 consisted of 46 regulatory positions. The proposed regulatory guide consists of 3 positions for a net reduction of 43 regulatory positions.

The proposed action also provides an opportunity to incorporate experience from the use of N45.2 and its daughter standards. Additionally, consolidation of design- and construction-phase quality assurance guidance should provide a more effective evaluation of compatibility between ANSI quality assurance requirements and the quality assurance requirements in the ASME Boiler and Pressure Vessel Code.

ANSI/ASME NQA-1-1983 represents a consensus document on requirements for quality assurance programmatic action. In a letter dated March 10, 1980, from Jack E. Vessely, Chairman, ASME Main Committee on Nuclear Quality Assurance to W. J. Dircks, Executive Director for Operations of the NRC, early endorsement by the NRC of ANSI/ASME NQA-1-1979 was requested since, according to the letter, many companies are anxious to use the standard. However, some members of the industry have indicated reservations regarding the usefulness of this document.

The proposed action establishes an NRC position on an existing national standard and therefore reduces uncertainty as to what the staff considers acceptable in the area of quality assurance requirements for the design and construction of nuclear power plants.

The cumulative benefit of the consolidation effort will be to eliminate redundant controls and to incorporate current NRC quality assurance guidance and practices for design and construction of nuclear power plants.

The controls described in the regulatory position of Revision 3 to Regulatory Guide 1.28 and the endorsement of ANSI/ASME NQA-1-1983 are considered to be generally equivalent, from a programmatic standpoint, to the controls described in Revision 2 to Regulatory Guide 1.28 and Regulatory Guides 1.58, 1.64, 1.74, 1.88, 1.123, 1.144, and 1.146, which endorse N45.2 and its daughter standards. As a result, applicants or licensees may commit either to this regulatory guide or to Revision 2 of Regulatory Guide 1.28 and the current issues of the regulatory guides that endorse the seven daugher standards. However, since ANSI/ASME NQA-1-1983 consolidates ANSI/ASME N45.2 and the seven programmatic ANSI/ ASME N45.2-series standards, these standards will be replaced with ANSI/ASME NQA-1-1983. Consequently, except in those cases in which an applicant proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the method described in Revision 3 to Regulatory Guide 1.28 will be used in the evaluation of all new (1) construction permit applications, (2) standard design approvals that can be referenced in construction permit applications, and (3) licenses to manufacture.

Consequences: Should members of the industry (utilities, architect/engineers, nuclear steam supply system suppliers, or vendors) wish to commit to this regulatory guide, indoctrination and training programs would have to be developed to ensure that the regulatory position of Revision 3 to Regulatory Guide 1.28 and the controls of NQA-1-1983 and how these controls are to be implemented are understood. Particular attention would have to be focused on clarifying the potential confusion in interpreting the degree to which the Basic Requirements and Supplements Sections, which are addressed as mandatory, and the nonmandatory guidance in ANSI/ASME NQA-1-1983 are to be implemented.

Also, present principal contractors and utilities that wish to commit to this guide will have to (1) conduct a detailed comparison of existing quality assurance controls and determine what changes are necessary to comply with the new regulatory guide and NQA-1, which, as a minimum, will involve changes from the regulatory guides that endorse N45.2 and its seven daughter standards to Revision 3 to Regulatory Guide 1.28 and ANSI/ASME NQA-1-1983; (2) make the necessary changes to their quality assurance manuals and detailed implementing procedures; (3) indoctrinate and train the work force on the correct interpretation of the changes and how they are to be implemented; (4) review their quality assurance programs with the NRC staff to ensure that they are meeting the spirit and intent of the regulatory guide and NQA-1; (5) where necessary, inform contractors, subcontractors, vendors, and subvendors of the changes, including any appropriate indoctrination and training; and (6) determine the impact on these suppliers relative to additional purchase costs. This may necessitate the utility having to maintain two sets of quality assurance manuals and two sets of implementing procedures (one set meeting the existing regulatory guides and standards and the other set meeting ANSI/ASME NQA-1-1983). This problem will be compounded because record-keeping, audits, and NRC inspections will have to keep in mind which system is being used. Architect/engineers or nuclear steam supply system suppliers working with present contracts to existing regulatory guides and standards and ANSI/ASME NQA-1-1983 would have record-keeping and implementation problems similar to the above.

Costs: For new applicants, committing to Revision 3 to Regulatory Guide 1.28 may result in lower costs

than committing to the regulatory guides presently endorsing N45.2 and the seven programmatic daughter standards. The reason is that some of the quality assurance requirements once considered important have now been made nonmandatory guidance in ANSI/ ASME NQA-1-1983. Also, the fact that certain requirements have been reduced or more clearly defined will also result in lower costs to a new applicant, e.g., the amount of radiographs to be retained for lifetime has been reduced. Only radiographs required for inservice inspections are to be maintained for lifetime pursuant to ASME Boiler and Pressure Vessel Code requirements. We regard this practice to be as stringent as or more stringent than the practice for other nondestructive examination records. Also, the records facility, which previously had to have a four-hour fire rating, now may have a two-hour fire rating provided certain provisions are met.

Applicants who are presently committed to implement the existing NRC quality assurance regulatory guides and ANSI/ASME standards and who elect to change and use Revision 3 to Regulatory Guide 1.28 and ANSI/ASME NQA-1-1983 will benefit somewhat from the examples in the above paragraph, but will encounter additional costs to offset such benefits. The additional costs will be revising the Safety Analysis Report (SAR) (or quality assurance topical report), quality assurance manuals, and implementing procedures and retraining personnel to accommodate this change. In addition, considerable time, effort, and resources will be expended in maintaining an accountability of outstanding purchase orders, items, and activities already under way as opposed to new activities with respect to the appropriate application of the previous commitment and the new commitment to Revision 3 to Regulatory Guide 1.28. The average SAR revision to accommodate ANSI/ASME NQA-1-1983 and the revised Regulatory Guide 1.28 would affect about 20 SAR pages and take about 16 staff hours for NRC review and acceptance or approximately $960 per plant (16 hours x $60/hour). It would take about 2 staff months for the average utility to review and revise the quality assurance program and implementing procedures to incorporate the revision for a cost of approximately $25,600 (40 days x 8 hours at $80/hour). Retraining the plant and corporate staff would cost about $32,000 (400 people x $80/hour). Therefore, the total cost for the average plant to change to Regulatory Guide 1.28 and ANSI/ ASME NQA-1-1983 would be about $58,560 ($960 NRC fees, $25,600 procedures review and revision, and $32,000 for retraining plant and corporate staff). The total cost to industry, should they all adopt ANSI/ASME NQA-1-1983 and Revision 3 to Regulatory Guide 1.28, could be in the range of $30,779,520 (79 licensees, 63 permit holders, and 25 nuclear steam supply system suppliers and architect/engineers = 167 x $58,560 = $9,779,520 and 700 subcontractors x $30,000 = $21,000,000).

4.4 Conclusions

In consideration of the above three alternatives, the NRC staff believes Alternative 3 will be the most viable alternative from which to base future quality assurance guidance upon meeting the Commission's regulations relative to quality assurance. This conclusion is primarily based upon offering the industry the choices of (1) committing to the N45.2-series standards and appropriate regulatory guides that endorse these standards or (2) committing to comply with Revision 3 to Regulatory Guide 1.28 endorsing ANSI/ ASME NQA-1-1983. In either case, they have the flexibility to develop alternatives meeting the Commission's quality assurance regulations, regulatory guides, and standards.

5. IMPACTS ON OTHER REQUIREMENTS

As discussed earlier in this Regulatory Analysis, the primary rationale for the proposed revision to Regulatory Guide 1.28 was to consolidate the programmatic standards without changing their intent, to eliminate certain redundancies and certain activities, and to reflect certain NRC quality assurance controls considered important by the staff to provide consistency in the quality assurance program review process. These new positions do not represent significant changes in regulatory practices. The staff has evaluated the guidance included in ANSI/ASME NQA-1-1983 and, coupled with the guidance included in the regulatory position in Revision 3 to Regulatory Guide 1.28, finds this is equivalent to the guidance, from a programmatic standpoint, contained in the N45.2 series of documents and the regulatory guides that endorsed them. The staff also endorses this consolidation effort as an acceptable method of meeting the requirements of paragraph 50.34(a)(7) and Appendix B to 10 CFR Part 50. Consequently, any impact on existing NRC requirements should be minimal.

6. CONSTRAINTS

Legal and institutional constraints, including issues related to enforceability, were discussed in Section 3, "Alternatives."

7. DECISION RATIONALE

7.1 NRC

Since current guidance for quality assurance programs is contained in a series of different standards and corresponding regulatory guides, the proposed action will be of value to the staff owing to the consolidation of a large number of requirements and recommendations concerning quality assurance into a single document. Additionally, consolidation of design- and construction-phase quality assurance guidance should provide a more effective evaluation of compatibility between ANSI quality assurance requirements and the quality assurance

requirements in the ASME Boiler and Pressure Vessel Code. By taking advantage of previous staff effort in conjunction with approval of ANSI/ASME NQA-1-1983, the proposed action establishes an NRC position on the recently approved standard with minimum impact on the staff.

7.2 Industry

ANSI/ASME NQA-1-1983 represents a consensus document on requirements for quality assurance programmatic action agreed to by the American National Standards Institute.

The proposed action establishes an NRC position on an existing national standard and therefore reduces uncertainty as to what the staff considers acceptable in the area of quality assurance requirements for the design and construction of nuclear power plants.

7.3 Public

The consolidation of quality assurance criteria could result in more effective reviews of nuclear power plant quality assurance programs.

The consolidation document could also result in improved quality assurance programs at nuclear power plants and hence increased safety for the public since the standard has eliminated certain activities considered to be ineffective in enhancing the overall quality or effectiveness of the quality assurance program. The financial impact on the public will be a slight increase in the cost of generating power as a result of any procedure modifications necessary to comply with this regulatory guide.

8. IMPLEMENTATION

8.1 Schedule for Implementing the Proposed Guidance

The methods described in Revision 3 to Regulatory Guide 1.28 (through endorsement of ANSI/ASME NQA-1-1983 and the ANSI/ASME NQA-1a-1983 Addenda) for complying with the provisions of Appendix B to 10 CFR Part 50 with regard to the establishment and implementation of the requisite quality assurance program are considered to be generally equivalent, from a programmatic standpoint, to the methods described by Revision 2 to Regulatory Guide 1.28 and Regulatory Guides 1.58, 1.64, 1.74, 1.88, 1.123, 1.144, and 1.146 (through endorsement of ANSI/ASME N45.2 and seven programmatic ANSI/ASME N45.2-series standards).

Applicants and licensees who have committed to ANSI/ASME N45.2 and the appropriate ANSI N45.2-series standards as addressed in the applicable regulatory guides may continue to follow ANSI/ASME N45.2 and the appropriate ANSI/ASME N45.2-series standards in lieu of ANSI/ASME NQA-1-1983. Applicants or licensees may commit to follow the ANSI/ASME N45.2-series standards or the ANSI/ASME NQA-1-1983 standard, but not a combination of the two.

Since ANSI/ASME NQA-1-1983 consolidates ANSI/ASME N45.2 and the seven programmatic ANSI/ASME N45.2-series standards, these standards will be replaced with ANSI/ASME NQA-1-1983. Consequently, except in those cases in which an applicant proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the method described in Revision 3 to Regulatory Guide 1.28 will be used in the evaluation of all new (1) construction permit applications, (2) standard design approvals that can be referenced in construction permit applications, and (3) licenses to manufacture.

8.2 Relationship to Other Existing or Proposed Requirements

The proposed Revision 3 to Regulatory Guide 1.28 does not represent an increase in regulatory requirements since it allows present applicants and licensees to continue the use of the N45.2-series standards if they had previously committed to those standards.

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